110TH CONGRESS
1ST SESSION

S. 1887

To amend title XVIII of the Social Security Act in order to ensure access to critical medications under the Medicare part D prescription drug program.

IN THE SENATE OF THE UNITED STATES

JULY 26, 2007

Mr. SMITH (for himself and Mr. KERRY) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XVIII of the Social Security Act in order to ensure access to critical medications under the Medicare part D prescription drug program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicare Access to Critical Medications Act of 2007".

SEC. 2. FORMULARY REQUIREMENTS WITH RESPECT TO CERTAIN CATEGORIES AND CLASSES OF DRUGS.

(a) REQUIRED INCLUSION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

(1) INITIAL LIST.—Section 1860D–4(b)(3) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)) is amended—

(A) in subparagraph (C)(i), by striking "The formulary" and inserting "Subject to subparagraph (G), the formulary"; and

(B) by inserting after subparagraph (F) the following new subparagraph:

"(G) INITIAL LIST OF REQUIRED DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

"(i) IN GENERAL.—Subject to clause (iv), the formulary must include all or substantially all drugs in the following categories and classes that are available as of April 30 of the year prior to the year which includes the date of enactment of the Medicare Access to Critical Medications Act of 2007:

"(I) Immunosuppressant.

"(II) Antidepressant.

"(III) Antipsychotic.

"(IV) Anticonvulsant.

"(V) Antiretroviral.

"(VI) Antineoplastic.

"(ii) NEWLY APPROVED DRUGS.—

"(I) IN GENERAL.—In the case of a drug in any of the categories and classes described in subclauses (I) through (VI) of clause (i) that becomes available after the April 30 date described in clause (i), the formulary shall include such drug within 30 days of the drug becoming available, except that, in the case of such a drug that becomes available during the period beginning on such April 30 and ending on the date of enactment of the Medicare Access to Critical Medications Act of 2007, the formulary shall include such drug within 30 days of such date of enactment.

"(II) USE OF FORMULARY MANAGEMENT PRACTICES AND POLICIES.—Nothing in this clause shall be construed as preventing the Pharmacy and Therapeutic Committee of a PDP sponsor from advising such sponsor on the clinical appropriateness of utilizing formulary management practices and policies with respect to a

newly approved drug that is required to be included on the formulary under subclause (I).

"(iii) UNIQUE DOSAGES AND FORMS.—A PDP sponsor of a prescription drug plan shall include coverage of all unique dosages and forms of drugs required to be included on the formulary pursuant to clause (i) or (ii).

"(iv) SUNSET.—The provisions of this subparagraph shall not apply after December 31 of the year which includes the date that is 5 years after the date of enactment of the Medicare Access to Critical Medications Act of 2007."

(2) REVIEW OF DRUGS COVERED UNDER THE MEDICARE PART D PRESCRIPTION DRUG PROGRAM.—Section 1860D–4(b)(3) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)), as amended by paragraph (1), is amended—

(A) in subparagraph (C)(i), by striking "subparagraph (G)" and inserting "subparagraphs (G) and (H)"; and

(B) by inserting after subparagraph (G) the following new subparagraph:

"(H) REQUIRED INCLUSION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

"(i) REQUIRED INCLUSION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

"(I) IN GENERAL.—Beginning January 1 of the year after the year which includes the date that is 5 years after the date of enactment of the Medicare Access to Critical Medications Act of 2007, PDP sponsors offering prescription drug plans shall be required to include all unique dosages and forms of all or substantially all drugs in certain categories and classes, including the categories and classes described in subclauses (I) through (VI) of subparagraph (G)(i), on the formulary of such plans within 30 days of the drug becoming available.

"(II) REGULATIONS.—Not later than January 1 of the year after the year which includes the date that is 4 years after the date of enactment of the Medicare Access to Critical Medications Act of 2007, the Secretary

shall issue regulations to carry out this clause.

"(ii) PERIODIC REVIEW.—The Secretary shall establish procedures to provide for periodic review of the drugs required to be included on the formulary under clause (i).

"(iii) UPDATING.—

"(I) IN GENERAL.—The Secretary may update the list of drugs required to be included on the formulary under clause (i) if the Secretary determines, in accordance with this clause, that updating such list is appropriate.

"(II) ADDING CATEGORIES OR CLASSES.—In issuing the regulations under clause (i) and updating the list in order to add a drug in a category or class to the list of drugs required to be included on the formulary under such clause, the Secretary shall consider factors that justify requiring coverage of drugs in a certain category or class, including the following:

"(aa) Whether the drugs in a category or class are used to treat a disease or disorder that can cause significant negative clinical outcomes to individuals in a short timeframe.

"(bb) Whether there are special or unique benefits with respect to the majority of drugs in a given category or class.

"(cc) High predicted drug and medical costs for the diseases or disorders treated by the drugs in a given category or class.

"(dd) Whether restricted access to the drugs in the category or class has major clinical consequences for individuals enrolled in a prescription drug plan who have a disease or disorder treated by the drugs in such category or class.

"(ee) The potential for the development of discriminatory

formulary policies based on the clinical or functional characteristics of such individuals and the high cost of certain drugs in a category or class.

"(ff) The need for access to multiple drugs within a category or class due to the unique chemical action and pharmacological effects of drugs within the category or class and any variation in clinical response based on differences in such individuals' metabolism, age, gender, ethnicity, comorbidities, drug-resistance, and severity of disease.

"(gg) Any applicable revisions that have been made to widely-accepted clinical practice guidelines endorsed by pertinent medical specialty organizations.

"(III) REMOVAL OF CATEGORIES OR CLASSES.—In updating the list in order to remove a drug in a category or class from the list of drugs re-

quired to be included on the formulary under clause (i), the Secretary may remove a drug from such list in the case where the Secretary determines that widely-accepted clinical practice guidelines endorsed by pertinent national medical specialty organizations indicate that, for substantially all drugs in the category or class, restricting access to such drugs is unlikely to result in adverse clinical consequences for individuals with conditions for which the drugs are clinically indicated.".

(b) LIMITATION OF UTILIZATION MANAGEMENT TOOLS FOR DRUGS IN CERTAIN CATEGORIES AND CLASSES.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended—

(1) in paragraph (1)(A), by striking "A cost-effective" and inserting "Subject to paragraph (3), a cost-effective"; and

(2) by adding at the end the following new paragraph:

"(3) LIMITATION OF UTILIZATION MANAGEMENT TOOLS FOR DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

"(A) IN GENERAL.—A PDP sponsor of a prescription drug plan may not apply a utilization management tool, such as prior authorization or step therapy, to the following:

"(i) During the period beginning on the date of enactment of this paragraph and ending on December 31 of the year which includes the date that is 5 years after such date of enactment—

"(I) a drug in a category or class described in subsection (b)(3)(G)(i)(V); and

"(II) a drug in a category or class described in subclause (I), (II), (III), (IV), or (VI) of subsection (b)(3)(G)(i) in the case where an enrollee was engaged in a treatment regimen using such drug in the 90-day period prior to the date on which such tool would be applied to the drug with respect to the enrollee under the plan or the PDP sponsor is unable to de-

termine if the enrollee was engaged in such a treatment regimen prior to such date.

"(ii) Beginning January 1 of the year after the year which includes the date that is 5 years after the date of enactment of this paragraph—

"(I) a drug in a category or class described in subsection (b)(3)(G)(i)(V), if such drug is required to be included on the formulary under subsection (b)(3)(H); and

"(II) a drug in any other category or class required to be included on the formulary under subsection (b)(3)(H) in the case where an enrollee was engaged in a treatment regimen using such drug in the 90-day period prior to the date on which such tool would be applied to the drug with respect to the enrollee under the plan or the PDP sponsor is unable to determine if the enrollee was engaged in such a treatment regimen prior to such date.

"(B) STATEMENT OF EVIDENCE BASE FOR APPLICATION OF UTILIZATION MANAGEMENT TOOL.—In the case where a utilization management tool is applied to a drug in a category or class required to be included on a plan formulary under subparagraph (G) or (H) of subsection (b)(3), the PDP sponsor of such plan shall provide a statement of the evidence base substantiating the clinical appropriateness of the application of such tool.".

(c) RULE OF CONSTRUCTION.—Nothing in the provisions of this section, or the amendments made by this section, shall be construed as prohibiting the Secretary of Health and Human Services from issuing guidance or regulations to establish formulary or utilization management requirements under section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) as long as they do not conflict with such provisions and amendments.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to contract years beginning on or after January 1, 2008.

SEC. 3. APPEALS REQUIREMENTS FOR CERTAIN CATEGORIES AND CLASSES OF DRUGS.

(a) COVERAGE DETERMINATIONS AND RECONSIDERATION.—Section 1860D–4(g) of the Social Security Act

(42 U.S.C. 1395w–104(g)) is amended by adding at the end the following new paragraph:

"(3) REQUEST FOR A DETERMINATION OR RECONSIDERATION FOR THE TREATMENT OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

"(A) IN GENERAL.—In the case where an individual enrolled in a prescription drug plan disputes a utilization management requirement, an adverse coverage determination, a reconsideration by a PDP sponsor of a prescription drug plan, or an adverse reconsideration by an Independent Review Entity with respect to a covered part D drug in the categories and classes required to be included on the formulary under subparagraph (G) of subsection (b)(3) or under the regulations issued under subparagraph (H) of such subsection, the PDP sponsor shall continue to cover such prescription drug until the date that is not less that 60 days after the latest of the following has occurred:

"(i) The enrollee has received written notice of an adverse reconsideration by a PDP sponsor.

"(ii) In the case where an enrollee has requested reconsideration by an Inde-

pendent Review Entity, such Entity has issued an adverse reconsideration.

"(iii) In the case where an appeal of such adverse reconsideration has been filed by the individual, an administrative law judge has decided or dismissed the appeal.

"(B) DEFINITION OF INDEPENDENT REVIEW ENTITY.—In this paragraph, the term 'Independent Review Entity' means the independent, outside entity the Secretary contracts with under section 1852(g)(4), including such an entity that the Secretary contracts with in order to meet the requirements of such section under section 1860D–4(h)(1).".

(b) APPEALS.—Section 1860D–4(h) of the Social Security Act (42 U.S.C. 1395w–104(h)) is amended—

(1) in paragraph (2), by striking "A part D" and inserting "Subject to paragraph (4), a part D"; and

(2) by adding at the end the following new paragraph:

"(4) TREATMENT OF APPEALS FOR DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

"(A) IN GENERAL.—A part D eligible individual who is enrolled in a prescription drug

plan offered by a PDP sponsor may appeal under paragraph (1) a determination by such sponsor not to provide coverage of a covered part D drug in a category or class required to be included on the formulary under subparagraph (G) of subsection (b)(3) or under the regulations issued under subparagraph (H) of such subsection at any time after such determination by requesting a reconsideration by an Independent Review Entity.

"(B) DEFINITION OF INDEPENDENT REVIEW ENTITY.—In this paragraph, the term 'Independent Review Entity' has the meaning given such term in subsection (g)(3)(B).".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to contract years beginning on or after January 1, 2008.

SEC. 4. DATA REPORTING REQUIREMENTS FOR CERTAIN CATEGORIES AND CLASSES OF DRUGS UNDER THE MEDICARE PART D PRESCRIPTION DRUG PROGRAM.

(a) IN GENERAL.—Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) is amended by adding at the end the following new subsection:

"(l) DATA REPORTING FOR CERTAIN CATEGORIES AND CLASSES OF DRUGS.—

"(1) IN GENERAL.—A PDP sponsor offering a prescription drug plan shall disclose to the Secretary (in a manner specified by the Secretary) data at the plan level on the number of—

"(A) favorable and adverse decisions made with respect to exceptions requested to formulary policies—

"(i) during the period beginning on the date of enactment of this subsection and ending on December 31 of the year which includes the date that is 5 years after such date of enactment, for each of the categories and classes of drugs described in subclauses (I) through (VI) of subsection (b)(3)(G)(i); and

"(ii) beginning January 1 of the year after the year which includes the date that is 5 years after such date of enactment, for each of the categories and classes of drugs required to be included on the formulary under the regulations issued under subsection (b)(3)(H);

"(B) favorable and adverse coverage determinations made with respect to each of such categories and classes during the applicable period;

"(C) favorable and adverse reconsiderations made by a PDP sponsor with respect to each of such categories and classes during the applicable period;

"(D) favorable and adverse reconsiderations made by an Independent Review Entity (as defined in subsection (g)(3)(B)) with respect to each of such categories and classes during the applicable period; and

"(E) appeals made to an administrative law judge and the decisions made on such appeals with respect to each of such categories and classes during the applicable period.

"(2) ANNUAL REPORT.—The Secretary shall—

"(A) submit an annual report to Congress containing the data disclosed to the Secretary under paragraph (1); and

"(B) publish such report in the Federal Register.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to contract years beginning on or after January 1, 2008.

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